EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

23 September 2020
EMA/HMPC/404030/2020
Human Medicines Division

Committee on Herbal Medicinal Products (HMPC)

Minutes for the meeting on 6-8 July 2020

Chair: E. van Galen, Vice-Chair: E. Svedlund

Disclaimers

Some of the information contained in this set of minutes is considered commercially confidential or sensitive and therefore not disclosed.

Of note, this set of minutes is a working document primarily designed for HMPC members and the work the Committee undertakes.

Note on access to documents

Some documents mentioned in the minutes cannot be released at present following a request for access to documents within the framework of Regulation (EC) No 1049/2001 as they are subject to on-going procedures for which a final decision has not yet been adopted. They will become public when adopted or considered public according to the principles stated in the Agency policy on access to documents (EMA/127362/2006).

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1. Introduction

1.1. Welcome and declarations of interest of members, alternates and experts

In accordance with the Agency's policy on handling of declarations of interests of scientific Committees' members and experts, based on the declarations of interest submitted by the Committee members, alternates and experts and based on the topics in the table of decisions of the current meeting, the Committee Secretariat announced that no restriction in the involvement of meeting participants in upcoming discussions was identified.

Participants in this meeting were asked to declare any changes, omissions or errors to their declared interests and/or additional restrictions concerning the matters for discussion. No new or additional interests or restrictions were declared with regard to topics on the agenda.

Discussions, deliberations and voting took place in full respect of the restricted involvement of Committee members and experts in line with the relevant provisions of the Rules of Procedure and as included in the list of participants.

End of membership:

- Paediatric medicine, Silvia Girotto (co-opted member) as of 3 June 2020

1.2. Adoption of agenda

The agenda for 6-8 July 2020 was adopted with minor additions (extension 5.2.1).

Time schedule for 6-8 July 2020 was endorsed with minor modifications.

1.3. Adoption of the minutes

HMPC minutes for 4-6 May 2020 were adopted and will be published on the EMA website.

2. EU herbal monographs and list entries for adoption

2.1. Status of HMPC/MLWP activities

2.1.1. Overview of HMPC/MLWP assessment work including the Rapporteurship distribution – Status in July 2020

Report: HMPC Chair
Action: for discussion
Document: Overview

Outcome:

HMPC noted status of assessment work. For substances on the work programme Rapporteurs informed on the likely availability of documents for the next meetings.

HMPC members noted that all reviews started in 2020 (calls for data ended latest end of June) will be put on the draft agenda in September.

In case of postponement of topics scheduled for the HMPC September meeting Rapporteurs were asked to inform secretariat and Chair before the first pre-mail (by 7 September 2020) to allow best adaptation of agenda and time-schedule.

2.1.2. Appointment of Rapporteurs and Peer-reviewers

Reviews
Fucus vesiculosus - New Rapporteur

Outcome:

HMPC endorsed re-appointment of the Rapporteur for Fucus vesiculosus monograph.

Members were invited to reconsider activities in view of workload to allow a wider distribution across the network.

2.2. Revised EU herbal monographs and list entries for final adoption

2.2.1. Monograph on Tanaceti parthenii herba and supporting documents

Action: for adoption
Documents: MO, AR, LoR; References: 0/108; Question to patient representatives, comments from patient representatives

Outcome:

Final revised EU herbal monograph and supporting documents adopted by majority vote (19 out of 24). The Norwegian delegate expressed a favourable position.

Divergent opinions: Sheena Kennedy, Karin Erika Svedlund, Burt H Kroes, Jacqueline Wiesner, Barbara Razinger

The committee had a final discussion with focus on the widened posology in comparison to the original monograph. In particular monograph section 4.2 and underlying documentation from various products as reflected in the AR were re-examined in terms of clarity for the safe use by self-medicating migraine patients taking into account patient representatives' comments.

Divergent opinions referred mostly to concerns with a maximum posology of 600 mg as regards safety, evidence of safe long-standing use and in particular the wording for a flexible posology. Furthermore, the use for prophylaxis and the duration of use gave reasons for concern.

2.2.2. Monograph on Thymi aetheroleum and supporting documents

Action: for adoption
Documents: MO, AR, LoR, Readers guidance; References: 122/137

Outcome:

Final revised EU herbal monograph and supporting documents adopted by consensus. The Norwegian delegate did not vote. The existing list entry was not changed.

After peer-review members discussed the documentation available for the evidence of the cutaneous use versus the oral use and an additional explanation in the AR was agreed.

Furthermore, the applicability of available genotoxicity data for only one chemotype of the essential oil was debated. The subsequent possibility for inclusion of not only the cutaneous use but also the oral use into the list entry was raised, which had not been proposed for the draft revision. Other issues raised were the risk for laryngospasm in particular in children in analogy to other herbal drugs (but Th. aetheroleum only indicated >18 years) and the plausibility of strength/ posology such as for use as bath additive.

2.3. Revised EU herbal monographs and list entries for public consultation

None

2.4. Reviewed EU herbal monographs and list entries for decision on revision

None

2.5. EU herbal monographs, list entries and public statements for final adoption

2.5.1. Monograph on Herniariae herba and supporting documents

Action: for adoption
Documents: MO, AR, LoR, OoC, Readers guidance; References: 35/24

Outcome:

Final EU herbal monograph and supporting documents adopted by majority vote (23 out of 24). The Norwegian delegate expressed a favourable position.

Divergent opinion: Wojciech Dymowski

HMPC members noted final amendments introduced in the assessment report. Concerns were raised regarding no documented duration of use (standard 2 weeks in the monograph) and the missing evidence for the use of the single substance (only in combination with other diuretic plants). The latter is also the reason for a divergent position.

2.6. EU herbal monographs, list entries and public statements for adoption for release for public consultation

2.6.1. Monograph on Menyanthes trifoliata folium and supporting documents

Action: for adoption
Documents: MO 1st proposal, MO 2nd proposal, AR, LoR, Readers guidance; References: 77/77

Outcome:

Adoption postponed.

Changes were introduced in the monograph and one version agreed. The Rapporteur was asked to align the Assessment report accordingly.

Documents to be finalised according to the discussion and transmitted for peer-review prior to possible adoption for release for public consultation at the **HMPC September** meeting.

Timetable:

Documents to be sent to peer-reviewer: **18 August 2020**

Peer-review documents to be sent to Rapporteur: **01 September 2020**

Final documents to be included latest in 2nd pre-mail: **15 September 2020**

The Rapporteur re-discussed with the committee details on the available evidence including plausibility and practicability of strength/posology for some traditionally used substances and indications in view of comparable herbal substances such as Harpagophytum and possible pharmacological effects behind. Agreement was found on the monograph content.

2.6.2. Monograph on Saccharomyces cerevisiae CBS 5926 and supporting documents

Action: for adoption
Documents: MO, AR, LoR; References: 2/214

Outcome:

Adoption postponed.

Changes in the monograph and AR including reference to the Ph. Eur. monograph on live biotherapeutic products (3053) were presented.

No majority was found to support the release for public consultation because of classification considerations (herbal vs biological MP).

The Rapporteur was asked to contemplate on an appropriate justification for a PS for finalisation of assessment and explanation why a monograph is not established in line with HMPC procedures.

Several members expressed support for publication of the AR as Annex to a PS as it can facilitate national assessments.

2.7. EU herbal monographs, list entries and public statements - post finalisation

None

3. Referral procedures

None

4. Guidelines and guidance documents

4.1. Non-clinical/clinical safety and efficacy and multidisciplinary

4.1.1. Public statement on the use of herbal medicinal products containing estragole

Action: for information
Documents: Draft revised PS, Comments received

Outcome:

HMPC noted comments received by Interested parties. Rapporteurs to prepare an overview of comments for more detailed discussion in September and finalisation of the PS before coordination within EMA and with EDQM.

HMPC agreed to resume assessment work on Foeniculi amari fructus, Foeniculi amari fructus aetheroleum, Foeniculi dulcis fructus (all revision) and Species digestivae/stomachicae (new assessment) (discussion on drafts scheduled for November).

4.1.2. Public statement on the contamination of herbal medicinal products/traditional herbal medicinal products with pyrrolizidine alkaloids (EMA/HMPC/328782/2016)

Action: for discussion
Document: See 4.1.3.

Outcome:

See 4.1.3.

4.1.3. Public statement on the use of herbal medicinal products containing toxic, unsaturated pyrrolizidine alkaloids (PAs) (EMA/HMPC/893108/2011)

Action: for adoption
Document: Draft Revised combined public statement

Outcome:

Draft Public statement with changes adopted by consensus for 3 months public consultation.

HMPC secretariat to publish after editorial review the draft revised PS now also addressing contamination with PAs not intrinsically contained in active substances of (T)HMPs as previously communicated in another PS (EMA/HMPC/328782/2016).

Some final adaptations in the conclusions (such as regarding 'short term use') were presented, discussed and agreed. Although some members raised doubts on the use of limited animal data for human risk assessment without having human data, the conclusions- harmonised between both previous statements- were agreed by consensus.

It was noted that for the final version interim wordings e.g. regarding the testing method to be applied will have been to be adapted according to latest status of the Ph. Eur. method finalisation.

4.2. Quality

4.2.1. Guideline on quality of herbal medicinal products/traditional herbal medicinal products (EMA/HMPC/201116/2005 Rev. 3)

Action: for discussion
Documents: Draft revised Guideline, OoC

Outcome:

Postponed. Options for detailed discussions before the Q DG re-activation were discussed and HMPC agreed that several sessions between few quality experts are required for detailed discussion and finalisation. Small group (lead NL and DE) to organise a primary meeting with few already involved quality experts. As necessary a follow-up with advanced overviews of comments will be organised with the HMPC secretariat before next discussion at the **HMPC September** meeting.

4.2.2. Guideline on specifications: test procedures and acceptance criteria for herbal substances, herbal preparations and herbal medicinal products/traditional herbal medicinal products (EMA/HMPC/162241/2005 Rev. 3)

Action: for information
Document: Revised Guideline

Outcome:

Postponed. See also 4.2.1.
After advance with the Quality GL Rapporteurship and next steps for finalisation to be agreed at the **HMPC September** meeting.

4.3. Regulatory / Procedural

None

4.4. Report on HMPC Drafting Groups activities

4.4.1. Quality DG

None

4.4.2. ORGAM DG

None

5. Organisational, regulatory and methodological matters

5.1. Mandate and organisation of the HMPC

5.1.1. Strategic Review and Learning Meetings

Germany Presidency meeting – September 2020
Action: for information

Outcome:

HMPC noted the invitation and first information by the German delegate on the SRLM under the DE presidency which will be organised 3-4 September via video conference. A draft agenda will be distributed in due course.

5.1.2. Co-opted member (paediatrics)

Report: HMPC Chair
Action: for discussion
Documents: Procedure for the nomination and appointment of co-opted members of the CHMP, CVMP and HMPC, Expertise of HMPC members

Outcome:
HMPC confirmed the need for additional expertise in paediatrics with some focus not only on clinical assessment but also medicinal practice and practical experiences in using THMPs in children.
Call for nominations of candidates for election at the HMPC September meeting will be sent out to HMPC members for search within the network and beyond. Additionally, the PDCO will be consulted.

5.1.3. Divergent positions at CXMP

Action: for discussion
Document: Presentation

Outcome:

HMPC noted a presentation on alignment of practice between committees regarding procedural aspects in the virtual meeting environment how to submit the grounds for divergent positions in electronic format and in case of written procedure or proxy.

5.1.4. Organisation of September 2020 HMPC meeting

Action: for information
Document: Information from EMA website

Outcome:

HMPC noted that the September meeting will be virtual and that all current arrangements in terms of remote versus F2F meetings apply until the end of September.

EMA will take a decision at later stage what the approach will be taken after October.

5.2. EMA Scientific Committees or CMDh-v

5.2.1. Scientific Coordination Board Meeting

Report: HMPC Chair
Action: for information
Documents: Draft Minutes 07 May 2020, Draft agenda 19 October 2020

Outcome:

HMPC noted topics discussed at the Scientific Coordination Board in May and the agenda for the upcoming October meeting.

5.3. Coordination with EMA Working Parties/Working Groups/Drafting Groups

None

5.4. Cooperation within the EU regulatory network

5.4.1. Coordination with European Pharmacopoeia

- EDQM 13A expert group meeting
  Report: M Bald
  Action: for information
  Document: SoD

  Outcome:

  HMPC noted summaries of decisions for the latest Group 13A meeting and other topics highlighted by the EDQM observer including timelines for finalisation and coming into force of the PA assay method.

  HMPC discussed latest developments on various topics relevant from an HMPC perspective including revision of Ph. Eur. monographs on Menthae aetheroleum (no changes of pulegone/menthofuran in view of HMPC PS), Sabalis serrulatae fructus (definition/specification, active principles) as well as limitation/assessment of animal contamination in herbal drugs vis-a-vis foreign matter standard requirements.

  Regarding the PA assay umbrella method the likely schedule for final adoption, publication and coming into force (January 2022) were communicated.

5.4.2. Coordination with the European Commission

- Planned COMMISSION REGULATION (EU) amending Annex III to Regulation (EC) No 1925/2006 as regards botanical species containing hydroxyanthracene derivatives
  Report: HMPC Chair
  Action: for information
  Documents: HADs Article 8 Safety Concerns, HMPC letter to EC, Outcome written procedure

  Outcome:

  HMPC noted final letter to EC on HAD, that was agreed via written procedure.

  After HMPC written procedure (adopted by consensus) and editorial amendment the letter had been transmitted to the Commission on 29 May 2020.

- Cannabis for medicinal use
  Report: HMPC Chair
  Action: for discussion

5.5. Cooperation with International Regulators

None

5.6. Contacts of the HMPC with external parties and interaction with the Interested Parties to the Committee

5.6.1. AESGP –hearing in November 2020

Report: HMPC Chair
Action: for information
Outcome:

HMPC agreed to organise a hearing with AESGP in November 2020.

Independent from the possibility to hold a face to face meeting, the annual hearing with AESGP is scheduled for the HMPC November meeting (likely day 3 of the plenary).

5.6.2. AESGP proposal for the 2nd revision of EU Monograph on Sennae folium to align with Ph. Eur.

Report: HMPC Chair
Action: for discussion
Outcome:

(1) HMPC agreed that no urgent revision of EU Monograph on Sennae folium is required.

Reference to the Ph. Eur. monograph ('as amended') in EU monograph section 2 is considered sufficient. Appropriate conversion factors for the quantification of HADs have to be clarified for individual products.

(2) The HMPC did not agree on a change of the review/ revision procedure as regards urgency of adaptation to analytical procedure changes in corresponding Ph. Eur. monographs.

Adherence to up-to-date quality standards according to Ph. Eur. and consequences for the specification/declaration should be sorted for individual products with the NCAs where products are (to be) registered/authorised.

5.6.3. EUCOPE – possible hearing

Report: HMPC Chair
Action: for information
Outcome:

HMPC agreed on the relevance of the proposed topics and to organise a hearing with EUCOPE in the first half of 2021.

HMPC secretariat to propose a hearing with Eucope between January and May 2021 taking into account some recent developments affecting committee operations in general as well as the proposed topics in particular.

5.7. Work plan

5.7.1. HMPC work plan 2020

Report: HMPC Chair, HMPC Vice Chair
Action: for discussion
Document: Work plan 2020, Annex 1, Annex 2 – current status July 2020

Outcome:

HMPC noted status of activities planned for 2020.

Recent developments as regards topic 2-1-2 (Involvement of patient representatives, 2-1-3 in particularly initiatives regarding use in children as well as 2-2-1 (herbal specific curricula trainings within the NTC framework) were shortly presented (see also agenda points 2.2.1 and 5.6)).

All topic leads will report on the current status of their projects at the HMPC September meeting in order to agree on activities until the last meeting in 2020.

- Activity area 2-1-3: Use of PhV, non-clinical and real-world data for HMPC relevant safety assessments
  Report: HMPC Chair
  Action: for discussion
  Document: Proposal

  Outcome:

  HMPC noted the comments/proposals regarding HMPC work plan topic 2-1-3. However, as the topic lead and co-opted member (paediatrics) has just resigned, the topic was not further discussed and the project participants asked to propose an appropriate follow-up for re-discussion at the **HMPC September** meeting.

- Activity area 2-2-1: Development of training on assessment of applications for herbal medicinal products
  Report: HMPC Vice Chair
  Action: for discussion
  Document: Presentation

  Outcome:

  HMPC noted presentation on the development of training on assessment of applications for herbal medicinal products.

  HMPC noted the outcome of the recent steering group meetings planning the next training developments for 2020 ('Introduction to the legal background of (T)HMP applications' and 'Use of QRD templates for SmPC, labelling and patient information for MRP/DCP for HMPs). The instructions on how non-NCA members can register for an account in the EU NTC Learning Management System platform (allowing them to register for future training and to access previous training) was also noted.

5.8. Planning and reporting

5.8.1. Future-proofing - Human Medicines – Committees

Action: for discussion
Document: Presentation

Outcome:

HMPC welcomed presentation of the new organisational structure and future development of Human Medicines Division.

Key features regarding the new EMA operating model as well as expected benefits for the operation of scientific committees and their supporting secretariats were presented.

5.9. Legislation and regulatory affairs

None

5.10. Questions from members

None

6. EU herbal monographs and list entries in preparation

6.1. Revision of EU herbal monographs and list entries in preparation for adoption after public consultation

6.1.1. Monograph on Millefolii herba and supporting documents

Action: for discussion
Documents: Draft MO, LE, AR, LoR; References: 59/73

Outcome:

HMPC members are invited to forward any information on herbal medicinal products containing thujone to the Rapporteur.

Rapporteur to finalise the documents (revised monograph and new list entry) for peer review and possible **final adoption** at the **HMPC September** meeting.

Timetable:

Documents to be sent to peer-reviewer: **18 August 2020**

Peer-review documents to be sent to Rapporteur: **01 September 2020**

Final documents to be included latest in 2nd pre-mail: **15 September 2020**

Two items were discussed: (1) reliable information on the thujone content in Millefolii herba and aetheroleum and subsequent exposure values vis-a-vis the posology in the monograph and (2) the inclusion of a standard herbal tea preparation into the monograph.

6.2. Revision of EU herbal monographs and list entries in preparation for public consultation

None

6.3. Review of EU herbal monographs and list entries in preparation for decision on revision

6.3.1. Monograph on Agropyri repentis rhizoma and supporting documents

Action: for discussion
Documents: Review report; References: 67/02

Outcome:

Rapporteur to introduce changes in the review report for **a second discussion at the HMPC September** meeting.

The value and relevance of some information in the summary was discussed. The Rapporteurs was asked to reduce information in the review report on what is new and

potentially relevant for changing the monograph as well as aligning proposals in the table and in the final conclusion.

6.3.2. Monograph on Carvi aetheroleum and supporting documents

Action: for discussion
Documents: Review report; References: 17/17

Outcome:

Rapporteur to introduce changes in the review report for **a second discussion at the HMPC September** meeting.

The committee discussed the relevance of new clinical safety data identified by the Rapporteur and whether they would change the previous assessment outcome and content of the existing monographs. While it was proposed to update the monographs, some members emphasised the limitations of new data and expressed not having major concerns regarding safety information in the existing monographs.

6.3.3. Monograph on Carvi fructus and supporting documents

Action: for discussion
Documents: Review report; References: 17/17

Outcome:

See 6.3.2

6.3.4. Monograph on Fucus vesiculosus and supporting documents - postponed

Outcome:
Postponed.

6.3.5. Monograph on Juniperi aetheroleum and supporting documents

Action: for discussion
Documents: Review report, readers guidance; References: 9/0

Outcome:

HMPC endorsed the Rapporteur's position that there is no new information available that could change the content of the monograph.

Rapporteur to finalise and clean/shorten the review report for peer review and **adoption** at the **HMPC September** meeting. Additional information or extracts from Minutes can be put in a reader's guidance.

Timetable:

Documents to be sent to peer-reviewer: **18 August 2020**

Peer-review documents to be sent to Rapporteur: **01 September 2020**

Final documents to be included latest in 2nd premail: **15 September 2020**

6.3.6. Monograph on Juniperi pseudo-fructus and supporting documents

Action: for discussion
Documents: Review report, readers guidance; References: 10/01

Outcome:

HMPC endorsed the Rapporteur's position that there is relevant new information available that could change the content of the monograph and therefore a revision of the complete package is advocated.

Rapporteur to modify and clean/shorten the review report according to the discussion for **adoption** at the **HMPC September** meeting.

Timetable:

Documents to be sent to peer-reviewer: **18 August 2020**

Peer-review documents to be sent to Rapporteur: **01 September 2020**

Final documents to be included latest in 2nd premail: **15 September 2020**

Beside a new preparation having a 30-years documentation a couple of other new pieces of information suggest the update of the monograph and supporting documents.

6.3.7. Monograph on Lavandulae aetheroleum and supporting documents

Action: for discussion
Document: Presentation

Outcome:

HMPC noted the Rapporteur's brief overview on new data and indication that there might be new information available that could change the content of the monograph.

Rapporteur to draft the review report for **a second discussion at the HMPC September** meeting.

6.3.8. Monograph on Lavandulae flos and supporting documents

Action: for discussion
Document: Presentation

Outcome:

See 6.3.7.

6.3.9. Monograph on Rosmarini aetheroleum and supporting documents - postponed

Outcome:
Postponed.

6.3.10. Monograph on Rosmarini folium and supporting documents - postponed

Outcome:
Postponed.

6.3.11. Monograph on Solidaginis virgaureae herba and supporting documents - postponed

Outcome:
Postponed.

6.3.12. Monograph on Colae semen and supporting documents

Action: for discussion
Documents: Review report; References: 60/62

Outcome:

Rapporteur to finalise the report for peer review and according to the outcome of the peer review to prepare the report for **a second discussion** or possible **adoption** at the **HMPC September** meeting.

Timetable:

Documents to be sent to peer-reviewer: **18 August 2020**

Peer-review documents to be sent to Rapporteur: **01 September 2020**

Final documents to be included latest in 2nd premail: **15 September 2020**

HMPC members principally endorsed that there are no new data justifying the revision of the existing monograph. The Rapporteur was asked to reduce the number of references to those relevant for the content of the monograph and usually selected for ARs.

6.4. EU herbal monographs and list entries in preparation for adoption after public consultation

None

6.5. EU herbal monographs and list entries in preparation for adoption for release for public consultation

6.5.1. Monograph on Andrographidis paniculatae folium and supporting documents - postponed

Outcome:
Postponed.

6.5.2. Monograph on Centellae asiaticae herba and supporting documents - postponed

Outcome:
Postponed.

6.5.3. Monograph on Salviae miltiorrhizae radix et rhizoma and supporting documents - postponed

Outcome:
Postponed.

6.5.4. Monograph on Vaccinii macrocarpi fructus and supporting documents

Action: for discussion

Documents: Draft MO, AR, LoR; References: 51/234

Outcome:

HMPC agreed to keep the indications as proposed.

Rapporteur and Peer-reviewer to finalise the draft monograph with main focus on the exact content in sections 2 and 4.2.

HMPC secretariat to organise 3rd preparatory meeting of experts willing to support despite data gaps an advanced draft monograph to be presented for **9th discussion** at the **HMPC September** meeting.

HMPC discussed the data gaps for preparations that can be included in the monograph. A comprehensive proposal to finalise the draft for publication was requested from the Rapporteur and supporting task force. If monograph sections 2 and 4.2 are agreed between Rapporteur and Peer-reviewer and underlying information in the AR conclusive despite some data limitations, the adoption for release for publication may be considered at the September meeting.

7. Any other business

7.1. Topics for discussion

None

7.2. Documents for information

7.2.1. HMPC

Table of Decisions from HMPC meeting held on 4-6 May 2020

Overview of expertise of members HMPC and subgroups

Inventory of herbal substances for assessment work

Abbreviations in HMPC agendas/minutes

Common names of herbal substances in all languages

Final Monograph Overview

7.2.2. ARSP

- English template
- English summaries for publication
  - Rhei radix
  - Rhamni purshianae

No objections were raised before publication of the two new herbal summaries.

7.2.3. EU herbal monographs, list entries and public statements – on hold

- Monograph on Foeniculi amari fructus and supporting documents – awaiting Estragole PS finalisation

- Monograph on Foeniculi amari fructus aetheroleum and supporting documents – awaiting Estragole PS finalisation
- Monograph on Foeniculi dulcis fructus and supporting documents – awaiting Estragole PS finalisation
- Monograph on Species digestivae or species stomachicae and supporting documents - awaiting Estragole PS finalisation

7.2.4. Other

- Yichang Yang: Use of herbal drugs to treat COVID-19 should be with caution
- Monograph on Menthae piperitae aetheroleum and supporting documents - post adoption editorial changes
- Monograph on Menthae piperitae folium and supporting documents - post adoption editorial changes

List of participants

List of participants including any restrictions with respect to involvement of members / alternates/experts following evaluation of declared interests for the 6-8 July 2020 meeting.

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Emiel Van Galen	Chair	Netherlands	No interests declared	
Reinhard Länger	Member	Austria	No interests declared	
Patricia Bodart	Member	Belgium	No interests declared	
Darko Trumbetic	Alternate	Croatia	No interests declared	
Maria Yiannitsarou	Alternate	Cyprus	No interests declared	
Markéta Příhodová	Member	Czech Republic	No restrictions applicable to this meeting	
Marie Heroutova	Alternate	Czech Republic	No interests declared	
Steffen Bager	Member	Denmark	No restrictions applicable to this meeting	
Karoline Holm Felding	Alternate	Denmark	No restrictions applicable to this meeting	
Eeva Sofia Leinonen	Member	Finland	No interests declared	
Sari Koski	Alternate	Finland	No interests declared	
An Le	Member	France	No interests declared	
Jacqueline Wiesner	Member	Germany	No interests declared	
Ioanna Chinou	Member	Greece	No interests declared	
Zsuzsanna Bíróné Dr Sándor	Member	Hungary	No interests declared	
Sheena Kennedy	Member	Ireland	No restrictions applicable to this meeting	
Anna Maria Serrilli	Alternate	Italy	No interests declared	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Everaldo Attard	Member	Malta	No interests declared	
Burt H Kroes	Member	Netherlands	No interests declared	
Gro Anita Fossum	Alternate	Norway	No interests declared	
Wojciech Dymowski	Member	Poland	No interests declared	
Ana Paula Martins	Member	Portugal	No interests declared	
Carmen Purdel	Member	Romania	No interests declared	
Miroslava Petrikova	Member	Slovakia	No interests declared	
Barbara Razinger	Member	Slovenia	No interests declared	
Adela Núñez Velázquez	Member	Spain	No interests declared	
Karin Erika Svedlund	Member	Sweden	No interests declared	
Gert Laekeman	Co-opted member	Belgium	No interests declared	
Heidi Foth	Co-opted member	Germany	No interests declared	
Maria Helena Pinto Ferreira	Co-opted member	Portugal	No interests declared	
Melanie Bald	Observer	EDQM	No interests declared	
Steffi Collaerts	Expert - via Adobe*	Belgium	No interests declared	
Pierre Duez	Expert - via Adobe*	Belgium	No restrictions applicable to this meeting	
Barbara Toth	Expert - via Adobe*	Hungary	No interests declared	
Klaus Reh	Expert - via Adobe*	Germany	No interests declared	
Friederike Stolte	Expert - via Adobe*	Germany	No interests declared	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
A representative from the European Commission attended the meeting				
Meeting run with support from relevant EMA staff				

* Experts were only evaluated against the agenda topics or activities they participated in.